UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION

TINA JOHNSON	:	**DOCKET NO. 2:10 CV 404**
VS.	:	**JUDGE MINALDI**
TEVA PHARMACEUTICALS USA, INC., ET AL.	:	**MAGISTRATE JUDGE KAY**

MEMORANDUM RULING

Before the Court is a Motion for Judgment on the Pleadings [Doc. 71], filed by the defendants, Generics Bidco I, LLC, Qualitest Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc. (collectively, the "Generic Defendants"). The plaintiff, Tina Johnson, filed an Opposition [Doc. 74], and the Generic Defendants filed a Reply [Doc. 75].

BACKGROUND

Metoclopramide is a prescription drug used to treat gastroesophageal reflux disease. The Food and Drug Administration ("FDA") first approved the use of metoclopramide in tablets marketed under the brand name Reglan in 1980. Five years later, several companies, including the Generic Defendants, began manufacturing generic metoclopramide tablets.

On March 12, 2010, Ms. Johnson filed suit against the Generic Defendants, alleging that she suffered injuries after ingesting generic metoclopramide tablets from July 2002 through and until March 2009.[2] Ms. Johnson avers that as a result of ingesting these tablets, she developed a severe neurological condition known as tardive dyskinesia.[3] She asserts that the Generic Defendants are liable for her injuries under the Louisiana Products Liability Act ("LPLA").

[2] Complaint ¶¶ 3.02, 3.09-3.11 [Doc. 1].

[3] *Id.*

Specifically, she asserts causes of action under the LPLA for (1) defective design, (2) failure to warn, and (3) breach of express warranty. [4]

After this case was filed, the Supreme Court handed down a decision in *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011), a case strikingly similar to the case now before the court. In *Mensing,* the plaintiffs asserted that generic drug manufacturers were liable under state tort law for failing to include adequate warning labels on their products. 131 S. Ct. 2573-74. The Court held that the Federal Food, Drug, and Cosmetic Act (FDCA) preempted the plaintiffs' claims. *Id.* at 2572. The Court noted that the Hatch-Waxman Amendments to the FDCA require generic manufacturers to conform their product labeling to the labeling approved by the Food and Drug Administration ("FDA") for the brand-name, or reference listed, drug. 131 S. Ct. at 2574. It would be impossible for a manufacturer to comply with both the FDCA and a state law requiring different or stronger labels. *Id.* Accordingly, the Court held that such state law is preempted by the FDCA. *Id.* at 2572.

The Generic Defendants argue that the Ms. Johnson's claims are preempted under *Mensing* and accordingly request that the court dismiss her complaint in its entirety. In response, Ms. Johnson argues that her breach of warranty and design defect claims are unaffected by *Mensing.* She also requests leave to amend her complaint to add claims that the Generic Defendants failed to use warnings other than product labeling to alert her physicians of metoclopramide's side effects and that they failed to adopt changes to their product labeling mandated by the FDA in 2004 in a timely manner.

RULE 12(C) STANDARD

After a party has answered a complaint, the proper mechanism for removing a claim from

[4] *Id* ¶¶ 4.01-4.07.

the Court's consideration is a judgment on the pleadings under Federal Rule of Civil Procedure 12(c). The court evaluates motions for judgment on the pleadings in the same manner in which it evaluates Rule 12(b)(6) motions to dismiss. In ruling on a Rule 12(b)(6) or Rule 12(c) motion, the court accepts the plaintiff's factual allegations as true and construes all reasonable inferences in a light most favorable to the plaintiff or nonmoving party. *Gogreve v. Downtown Develop. Dist.*, 426 F. Supp.2d 383, 388 (E.D. La. 2006). Plaintiffs must plead enough facts to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1974 (2007). "Factual allegations must be enough to raise a right to relief above the speculative level...on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 1965. A court should only grant a motion for judgment on the pleadings when the plaintiff would not be entitled to relief under any set of facts the plaintiff could prove consistent with the complaint. *Johnson v. Johnson*, 385 F.3d 503, 529 (5th Cir. 2004).

ANALYSIS

To maintain a successful products liability action under the LPLA, a plaintiff must establish (1) that the defendant is a manufacturer of the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product "unreasonably dangerous"; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else. La. Rev. Stat. § 9:2800.54(A). The LPLA authorizes four theories of recovery: (1) construction or composition defect; (2) design defect; (3) inadequate warning; or (4) breach of express warranty. La. Rev. Stat. § 9:2800.52-54. A plaintiff may not recover from a manufacturer for damage caused by a product on the basis of any theory not set forth in the LPLA. *Jefferson v. Lead Industries, Ass'n., Inc.*, 106 F.3d 1245, 1250-51 (5th Cir. 1997). Ms. Johnson asserts that the Generic Defendants are

liable for failing to provide adequate warnings, for design defect, and for breach of express warranty. The court will address each claim in turn.

I. Failure to Warn

To successfully maintain a failure-to-warn claim under the LPLA, a plaintiff must demonstrate that the product in question has a potentially damage-causing characteristic and that the manufacturer failed to use reasonable care to provide an adequate warning about this characteristic. La.Rev.Stat. § 9:2800.57(A). In order to be adequate, the warning provided by a manufacturer "must both lead the ordinary user or handler to contemplate the danger in using the product (the warning component) and to either use it safely (the instruction component) or decline to use it." *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 271 (5th Cir. 2002). In addition, a manufacturer has a duty under the LPLA to exercise reasonable care to discover unknown risks posed by its product, and to exercise reasonable care in warning of those risks. La. Rev.Stat. § 9:2800.57(C).

In her initial complaint, Ms. Johnson asserts that the Generic Defendants failed to ensure that the labeling and package inserts accompanying their drugs contained adequate warnings. *Mensing* clearly forecloses these claims. Ms. Johnson, however, seeks leave to amend her complaint to add claims that the Generic Defendants failed to employ means other than product labeling to inform her physicians of the risks associated with the long-term use of metoclopramide and failed to implement label changes approved by the FDA in 2004 in a timely manner. She argues that because neither of these actions would have required the Generic Defendants to provide warnings different or in addition to those mandated by the FDA, claims addressing the Generic Defendants' alleged failure to take them are not preempted under *Mensing*.

A. Failure to Warn Using Communications Other than Product Labeling

FDA regulations define the term "label," to include:

> Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor. 21 C.F.R. § 202.1(l)(2) (2012).

In *Mensing*, the Court accepted the FDA's argument that "Dear Doctor" letters used to send additional warnings to prescribing physicians and other healthcare professionals qualify as "labeling" under the applicable regulations. 131 U.S. at 2576.

Ms. Johnson has not identified any means of communication that the Generic Defendants could have used to relate additional or more effective warnings to her physicians that would not likewise fall within the FDA's expansive definition of "labeling." All forms of labeling issued by generic manufacturers are subject to the "duty of sameness" identified by the Court in *Mensing*, and therefore any claim that a generic manufacturer failed to issue more or different labeling is preempted by the FDCA. Accordingly, the court denies her request to amend her complaint to include allegations that the Generic Defendants failed to use other communications to alert Ms. Johnson and her physicians of metoclopramide's side-effects. Any such claim would be preempted by the FDCA under *Mensing,* and amendment is therefore futile.

B. Failure to Implement 2004 Labeling Update

Ms. Johnson additionally asserts that the Generic Defendants failed to comply with their labeling duties under the FDCA by failing to update their labels to include

additional warnings approved by the FDA in 2004.[1] She argues that even if the FDCA preempts claims that the Generic Defendants should have used warnings different or in addition to those approved by the FDA, it does not preempt claims addressing their failure to include warnings mandated by the agency.

The court agrees. The Court in *Mensing* based its holding on impossibility preemption. 131 U.S. at 2578. The crux of the decision was that it would be impossible for generic manufacturers to fulfill both a state-law duty to strengthen the labels approved by the FDA for reference listed drugs and their duty under the FDCA to keep them the same. *Id.* Where the FDA has approved a change to the label for the reference listed drug, however, generic drug manufacturers would not violate the FDCA by implementing that change. Therefore, impossibility preemption would not apply to any requirement under the LPLA that the Generic Defendants update their product labels to reflect labeling changes made by the brand name manufacturer.

Nevertheless, the court finds that amendment would be futile because Ms. Johnson cannot state a plausible claim for relief based on the Generic Defendants' delay in adopting the 2004 labeling changes. The proposed amendment is wholly inconsistent with the allegations of Ms. Johnson's original complaint. The original complaint includes an allegation that the FDA-approved warning label for Reglan remained

[1] The 1985 label for Reglan/metoclopramide warned "that 'tardive dyskinesia . . . may develop in patients treated with metoclopramide,' and the drug's package insert added that 'therapy longer than 12 weeks has not been evaluated and cannot be recommended.'" *Mensing*, 131 S.Ct. at 2572 (quoting Physicians' Desk Reference, 1635-36 (41st ed. 1987)). The label remained unchanged until 2004, when the brand name manufacturer strengthened the warning by adding the statement, "[t]herapy should not exceed 12 weeks in duration." 131 S.Ct. at 2573. In 2009, the FDA ordered an even stronger warning: "Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases." *Id.*

"inadequate" until the FDA issued a "boxed warning" in 2009.[2] Essentially, therefore, Ms. Johnson seeks leave to amend her complaint to assert a claim that the Generic Defendants are liable for failing to update their label to one that was still inadequate.

Any claim that the stronger, but still inadequate, 2004 label would have prevented Ms. Johnson's injuries had the Generic Defendants timely adopted it is belied by her allegation that she continued to take metoclopramide until March of 2009.[3] Ms. Johnson states in her Memorandum in Opposition to the Generic Defendants' Motion for Judgment on the Pleadings that Teva implemented the label change on July 15, 2005.[4] Nevertheless, Ms. Johnson allegedly continued to ingest metoclopramide for three and a half more years, until the FDA again updated the label in February of 2009.[5] She therefore cannot plausibly claim that Teva's one-year delay in implementing the 2004 changes to the label proximately caused her injuries. Accordingly, her request to amend her complaint to include such a claim is denied.

II. Design Defect

Under Louisiana law, a product is considered unreasonably dangerous in design if at the time it left the manufacturer's control: (1) there existed an alternative design for the product that was capable of preventing the claimant's damage; and (2) the likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting the alternative design. La. Rev.Stat. § 9:2800.56.

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[2] Compl. ¶ 3.12.

[3] *See* Compl. ¶ 3.02

[4] Pl.'s Mem. in Opp. to Defs.' Mot. for J. on the Pleadings 7 [Doc. 74].

[5] Compl. ¶ 3.02.

Ms. Johnson initially alleges that the Generic Defendants could have employed an alternative packaging design that would have mitigated the risks posed by metoclopramide.[6] This, however, is merely another way of stating that the Generic Defendants failed to provide adequate warnings about the risks associated with the long term-use metoclopramide. As explained above, *Mensing* forecloses any such claim. The FDCA prohibits generic manufacturers from employing any labeling that contains information that differs from that contained in the labeling used by brand-name manufacturers. Under the FDCA, "labeling" includes any written material accompanying the product. 21 U.S.C. § 321(m) (2009). Accordingly, there was no alternative packaging design available to the Generic Defendants that could have conveyed stronger or different warnings about metoclopramide's side effects.

The FDCA likewise prevented the Generic Defendants from altering unilaterally the design of the drug itself. A generic drug manufacturer must ensure that its product has the same active ingredient, route of administration, dosage form, and strength as the reference listed drug already approved by the FDA, unless the manufacturer has received special permission from the FDA to alter any of the drug's characteristics. *See* 21 U.S.C. § 355(j) (2009). In *Mensing*, the Court held that "impossibility preemption" exists where federal law prohibits a private party from taking an action required by state law without first obtaining special approval from the federal government. 131 S.Ct. at 2579 ("The question for "impossibility is whether the private party could independently do under federal law what state law requires of it."). Accordingly, Ms. Johnson cannot show that an alternative drug design was available to the Generic Defendants, and her design defect claims will be dismissed as preempted.

[6] *See* Pl.'s Brief on the Impact of *Mensing* 21 [Doc. 60].

III. Breach of Warranty

La. Rev. Stat. § 9:2800.58 provides that a product is unreasonably dangerous if it fails to conform to an express warranty made by the manufacturer. The LPLA defines an "express warranty" to include any representation, statement of fact, or promise about a product's characteristics or qualities. La. Rev. Stat. § 9:2800.53(d). Ms. Johnson argues that the package inserts provided by the Generic Defendants contained false statements regarding the risks associated with the long-term use of metoclopramide. [7]

This claim falls directly within the scope of *Mensing*. Package inserts are labels within the meaning of the FDCA and are therefore subject to the "duty of sameness." *See* 21 U.S.C. § 321(m) (2009). The Generic Defendants could not have altered their package inserts without FDA approval. *See Mensing*, 131 S. Ct. at 2578. Accordingly, Ms. Johnson's breach of warranty claim will be dismissed.

IV. Failure to Withdraw from the Market

Ms. Johnson suggests that even if the Generic Defendants could not have changed the composition of their product, they could have avoided liability for defective design by declining to sell generic metoclopramide altogether.[8] Because nothing in the FDCA would have prevented the defendants from declining to sell metoclopramide, she argues that a claim arising out of their failure to do so would not be preempted under *Mensing*.[9]

The plaintiffs in *Mensing* raised the same "failure to withdraw" claim, without success, in their petition for rehearing. *See* Respondents' Petition for Rehearing, *Pliva, Inc. v. Mensing*, 131

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[7] *Id.* at 24.

[8] *See id.* at 8.

[9] *Id.*

S. Ct. 2567 (July 18, 2011) (No. 09-993), 2011 U.S. S. Ct. Briefs LEXIS 878, at *3-6. On remand, the Eighth Circuit interpreted the Supreme Court's ruling in *Mensing* to encompass the plaintiffs' failure-to-withdraw claims and vacated the portion of its earlier opinion that embraced the failure-to-withdraw theory. *See Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011), *and* 588 F.3d 603, 611 (8th Cir. 2009) ("The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product.").[10] This court likewise rejects Ms. Johnson's failure to withdraw argument and accordingly denies her leave to amend her complaint to assert it.

[10] The court notes that the First Circuit recently held that although *Mensing* forecloses failure -to-warn claims based on a generic manufacturer's failure to withdraw from the market, it does not prevent plaintiffs from asserting design defect claims based on the same theory. *See Bartlett v Mutual Pharmaceutical Co., Inc.*, No. 10-227, 2012 U.S. App. LEXIS 9050 at *12-13 (1st Cir. May 2, 2012). Even if a claim arising out of a generic drug manufacturer's failure to refrain from selling a drug approved for sale by the FDA would not be preempted by the FDCA, however, the court finds a manufacturer's mere failure to withdraw a product from the market is insufficient to establish a claim for design defect under Louisiana law. In order to recover on a defective design theory under La. Rev. Stat. § 9:2800.56, "a plaintiff claiming a product is unreasonably dangerous in design must establish that a feasible alternative design existed at the time the product left the manufacturer's control that would have prevented the plaintiff's injury and that the risk avoided by the alternative design outweighed the burden of its adoption." *Seither v. Winnebago Industries, Inc.*, 02-2091 (La. App. 4 Cir. 7/31/03); 853 So. 2d 37 (citing *Morgan v. Gaylord Container Corp.*, 30 F.3d 586, 590 (5th Cir.1994)). As stated above, Ms. Johnson cannot show that the Generic Defendants could have used an alternative design. Therefore, she cannot state a claim for defective design.

CONCLUSION

For the reasons stated herein, the Generic Defendants' Motion for Judgment on the Pleadings will be granted, and Ms. Johnson's complaint will be dismissed with prejudice.

Lake Charles, Louisiana, this 21 day of May 2012.

PATRICIA MINALDI
UNITED STATES DISTRICT JUDGE